REMARKS

This Response is submitted in reply to the Office Action mailed on July 17, 2007. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-696 on the account statement.

Claims 1-5 and 7-9 are pending. Claim 6 was previously canceled. In the Office Action, Claims 1-5 and 7-9 are rejected under 35 U.S.C. §102 and §103. For the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-5 and 7-9 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,207,638 to Portman ("*Portman*").

Independent Claim 1 recites, in part, a composition comprising a protein source consisting essentially of intact whey proteins in an amount ranging from 21 to 40% by total dry weight of the composition. Independent Claim 5 recites, in part a composition containing a protein source consisting essentially of intact whey proteins, wherein the intact whey proteins are administered in an amount of 0.1 to 0.8 g intact whey proteins per kg body weight during, before or after a standard meal. Applicants submit that *Portman* fails to disclose every element of the present claims.

In accordance with embodiments of the present invention, Applicants have surprisingly found that intact whey proteins significantly increase the production and/or secretion of insulin. For instance, administering to a person an effective amount of intact whey proteins enhances post-prandial insulinemia and/or decreases blood glucose levels. See, specification, page 5, lines 1-12. Moreover, Applicants have found that intact whey proteins induce a dramatic but short increase in plasma amino acids as opposed to proteins such as casein that are more slowly digested and which induce a mild by prolonged plateau of hyperaminoacidema. See, specification, page 4, lines 21-23.

By contrast to the present claims, *Portman* fails to disclose or suggest a composition containing a protein source consisting essentially of intact whey proteins as required, in part, by independent Claims 1 and 5. In fact, *Portman* teaches away from the use of intact whey proteins by teaching, for example, the use of casein that, as Applicants stated above, is more slowly

digested and induce a mild by prolonged plateau of hyperaminoacidema. See, *Portman*, column 5, lines 2-4. In addition, *Portman* sets forth in column 5, lines 2-4 and column 6, lines 10-12, protein in the form of GMP is also included. Thus, *Portman* does not disclose or even suggest the inventive feature of a protein source that includes only intact whey proteins.

The Office Action asserts, in response, that the claims do not necessarily omit other protein sources to be present since "consisting essentially of" language is not closed language. Applicants respectfully disagree. The transitional phrase "consisting essentially of" limits the scope of a claim to the specific materials or steps and those that do not materially affect the basic or novel characteristics of the claimed invention. See, MPEP 2111.02; *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). The Federal Circuit has also characterized a "consisting essentially of" claim as occupying a middle ground between closed claims of "consisting of" format and fully open claims of "comprising" format. See, *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 448 USPQ2d 1351, 1353-1354 (Fed. Cir. 1998).

Therefore, with regard to the present claims, the "consisting essentially of" language limits the protein source to intact whey proteins and those materials that do not materially affect the basic or novel characteristics of the claimed invention. Applicants respectfully submit that the casein disclosed in *Portman* materially affects the basic or novel characteristics of the claimed invention. As previously noted, Applicants distinguish casein from the intact whey proteins of the present invention by specifically noting that intact whey proteins induce a short, dramatic plasma amino acid increase compared to a prolonged plateau of hyperaminoacidema induced by proteins such as casein. Moreover, Applicants specifically compare the effects of intact whey protein versus casein in the specification. The results establish that intact whey proteins have increased bioavailability and higher maximal plasma concentration of C-peptide than casein. See, specification, page 9, line 20 to page 14, line 9. Therefore, use of the lesser effective casein as a protein source in the present claims would materially affect the novel characteristics of the claimed invention by essentially canceling out the positive effects of intact whey proteins described in Applicants' specification. Accordingly, the "consisting essentially of" language of the present claims is closed language that excludes casein as a possible material in Applicants' invention.

Moreover, since *Portman* fails to disclose or suggest a composition consistently essentially of intact whey protein, it follows that *Portman* also fails to disclose or suggest the specific amounts claimed, namely (a) 21 to 40% by total dry weight of the composition (Claim 1) and (b) 0.1 to 0.8 grams intact whey proteins per kilogram body weight (Claim 5).

In the Office Action, Claims 1-5 and 7-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Portman*, as cited above, in view of newly cited U.S. Pat. No. 6,875,459 to Kopf, et al. ("*Kopf*"). Applicants submit that, even if combinable, the cited references fail to disclose or suggest every element of the present claims.

As stated above, *Portman* fails to disclose or suggest multiple elements of the present claims. For example, *Portman* fails to disclose or suggest a composition containing a protein source consisting essentially of intact whey proteins as required, in part, by independent Claims 1 and 5. Moreover, *Portman* fails to disclose or suggest a protein source consisting essentially of intact whey proteins in an amount ranging from 21 to 40% by total dry weight of the composition as required, in part, by independent Claim 1. Further, *Portman* fails to disclose or suggest a protein source consisting essentially of intact whey proteins, wherein the intact whey proteins are administered in an amount of 0.1 to 0.8 g intact whey proteins per kg body weight as required, in part, by independent Claim 5.

Kopf fails to remedy these deficiencies. While it is arguable whether *Kopf* even teaches the use of a composition containing a protein source consisting essentially of intact whey proteins, *Kopf* clearly fails to disclose or suggest the specific amounts claimed, namely (a) 21 to 40% by total dry weight of the composition (Claim 1) and (b) 0.1 to 0.8 grams intact whey proteins per kilogram body weight (Claim 5). In fact, *Kopf* does not appear to disclose a nutritional or pharmaceutical composition in the first place. Rather, *Kopf* seems to be directed to isolating proteins rather than using specific proteins in nutritional or pharmaceutical compositions.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections of Claims 1-5 and 7-9 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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